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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,805	03/02/2002	Valeri V. Golovlev		2639

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LUEDEKA NEELY 7 GRAHAM , P.C.
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Knoxville, TN 37901

EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,805

Applicant(s)

GOLOVLEV, VALERI V.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 7, 8, 14 is acknowledged and has been entered.
2. Applicant's addition of claims 17-20 is acknowledged and has been entered.
3. Claims 1-20 are currently pending.
4. Claims 1-6, 9-11 have been withdrawn.

Rejections Withdrawn

5. Applicant's arguments, see pg 7, filed August 27, 2004, with respect to the rejections under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejections of claims 7-8 and 12-16 has been withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 7,8, 12-16, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al [US 5,846,708].

With respect to claims 7, 20, Hollis et al teach a method comprising applying a sample to a plurality of test sites having attached probes such that different test sites have probes that bind to different molecular structures, formed on a surface of an integrated circuit array sensor (column 4, lines 41-45), maintaining a constant preprogrammed temperature or running a

preprogrammed temperature profile (column 10, lines 18-25), acquiring an electronic signal from a plurality of pixels associated with the test sites (column 4, 60-65), and detecting the amplitude of the signals versus time from the test sites to determine which probes have interacted with an associated target molecular structure (column 7, lines 15-33). Hollis et al further teach that a circuit is coupled to the test sites using transistor switches using row and column addressing techniques employed, for example, in addressing dynamic random access memory (DRAM) or active matrix liquid crystal display (AMLCD) devices (column 5, lines 1-5). Hollis et al further teach using a stationary illumination beam with a reconfigurable "light-valve" 415 (shown in dotted lines in FIG. 17) such as a liquid-crystal display or switchable mirror array, which is illuminated with a laser or intense lamp. The illuminated "light-valve" is imaged onto the sensor array, with a lens system. The pixel elements in the "light-valve" are electronically switched "on" or "off" to select corresponding areas to be sensitized in the sensor array (column 13, lines 28-34). The targets may be tagged with luminescent or chemiluminescent or radiological material. The test sites containing hybridized tagged DNA emit radiation which is detected by the occurrence of an accumulation of charge in a region beneath a respective CCD gate (column 9, lines 38-45).

8. With respect to claims 8, the probes can be oligonucleotides or antibodies (column 4, lines 35-41).
9. With respect to claim 12, the detection step can comprise detecting an electronic signal at a constant temperature of the sample substance and the array sensor. Specifically, Hollis et al teach a desired synthesis temperature applied to wells where a reaction is desired (column 13, lines 50-55).

10. With respect to claim 15, the detection step comprises an electronic signal vs time (rate of hybridization) for each probe site (column 7, lines 15-33, column 14, lines 3-19).
11. With respect to claim 17, Hollis et al teach that the temperature can be kept at a temperature above the desired synthesis temperature (column 13, lines 50-55).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 13, 18, 19 are rejected under 35 U.S.C. 103(a) as being obvious over Hollis et al [US 5,846,708] in view of Atwood et al [US 5,602,756].

With respect to claims 13, 18, 19, Hollis et al teach a method comprising a detection step comprising detecting an electronic signal during a change of the temperature of the sample substance and the array sensor, as discussed above. Hollis et al do not teach that the change in temperature is stepwise.

Atwood et al, however, teach that generally it is desirable to change the sample temperature to the next temperature in the cycle as rapidly as possible for several reasons. First, the chemical reaction has an optimum temperature for each of its stages. Thus, less time spent at nonoptimum temperatures means a better chemical result is achieved. Another reason is that a minimum time for holding the reaction mixture at each incubation temperature is required after each said incubation temperature is reached. These minimum incubation times establish the

"floor" or minimum time it takes to complete a cycle. Any time transitioning between sample incubation temperatures is time which is added to this minimum cycle time. Since the number of cycles is fairly large, this additional time unnecessarily lengthens the total time needed to complete the amplification (column 2, lines 57 – column 3, line 5).

Therefore, it would have been obvious in the method taught by Hollis et al to have the detection step comprise a stepwise change in temperature, as suggested by Atwood et al, in order to achieve a better chemical result and to minimize the cycle times.

14. Claims 14, 16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al [US 5,846,708] in view of Ulanovsky [US 5,627,032].

With respect to claims 14, 16, 18 Hollis et al teach a detection step comprises detecting an electronic signal during a change of the temperature of the sample substance and the array sensor as discussed above (column 7, lines 15-33 and column 13, lines 43-47). Hollis et al do not teach a gradual change in temperature.

Ulanovsky, however, teaches that it is not always easy to determine the optimal temperature of the composite extension reaction a priori and that a practical way to do so is to decrease the temperature slowly (within a few minutes to a few tens of minutes) through the right range (column 21, lines 1-21).

Therefore, it would have been obvious to have a detection step comprising detecting an electronic signal during a change in temperature, as taught by Ulanovsky, in the method of Hollis et al, in order to determine the optimal temperature of the composite extension reaction.

Response to Arguments

15. Applicant's arguments with respect to claims 7-8, 12-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641



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12/20/04